Filing Objections and Requests for a Hearing on a Regulation or Order
(21 CFR Part 12.22)
OMB No. 0910-0184
SUPPORTING STATEMENT

00 APR 11 P6:09

SECTION A - JUSTIFICATION

1. Circumstances Necessitating Information Collection

The Federal Food, Drug and Cosmetic Act (21 U.S.C. 301-393) and other statutes enforced by FDA provide that:

Within thirty days after publication of a regulation or order pursuant to (21 U.S.C. 371 (e) (2) or other statutory sections) (Attachment A), any person adversely affected by such regulation of order may file objections thereto with the Secretary, specifying with particularity, the provisions of the regulation or order deemed objectionable, stating reasonable grounds, therefore, requesting a public hearing on such objection.

These statutory provisions have been implemented by an FDA regulation at 21 CFR 12.22. This FDA regulation sets forth conditions and format for submitting objections and requesting a public hearing on a specific regulation or order.

If an objecting party believes that factual information demonstrates that a regulation or order is not adequately supported by the record, it is appropriate for FDA to require that the objecting party describe the alleged deficiencies. Thus, any person adversely affected by a regulation or order may file objections and request a public hearing in accordance with 21 CFR 12.22 (Attachment B). The submission of objections and the request for a hearing must be done within the statutorily specified 30 days.

We are requesting OMB approval for the following citation:

21 CFR 12.22
Reporting. A format for reporting/filing objections/
Requests for a hearing on a regulation or order.

2. How, By Whom, Purpose of Collection

The information obtained is used by the agency to determine if a hearing is justified. It may also be used to justify modification or revocation of a regulation or order.

3. Consideration Given to Information Technology

The use of improved technology to reduce burden is not applicable to Filing Objections and Requests for a Hearing on a Regulation or Order.

4. Identification of Information

There is no similar information that can be used or modified for use. The information required in filing and objection or requesting a hearing on a regulation or order is not available from any other source than the person filing or requesting.

5. Small Businesses

This information collection does not impact on small businesses. FDA does, however, assist small business through the Office of Small Business, Scientific and Trade Affairs by means of the scientific and administrative staffs within the Center.

6. Less Frequent Information Collection

If these procedural requirements are not provided, citizens would be unable to determine how to go about filing an objection or requesting for a hearing on a regulation or order. Any person who is adversely affected by a regulation or order may file objections and request a public hearing.

7. Special Information Collection Circumstances

There are no special circumstances requiring the collection of information.

8. Outside Consultations

In accordance with 5 CFR 1320.8(d), on October 25, 1999 (64 FR 57467) a 60-day notice for public comment (Attachment C) was published in the Federal Register. No comments were received from the public.

9. Payment or Gift

No payment or gift is contemplated under the terms of this proposed information collection.

10. Confidentiality Provisions

No assurance of confidentiality has been provided except as generally considered in review guidelines in 21 CFR 20.61.

11. Privacy

There are no questions of a sensitive nature involved in Filing or Requesting a Hearing on a Regulation or Order.

12. Burden of Information Collection

Persons familiar with this process estimate an average of 20 hours to be expended in preparation of a submission. Calculated at an overall figure of $69/hour (includes professional, clerical work, and overhead), this amounts to $1,380 per submission. An average of 60 submissions per year equals a total expenditure of $82,800 for all respondents. The burden involved with preparing an objection was estimated by personnel in the agency familiar with the program. Past experience indicates that we receive approximately 60 submissions a year. The burden may vary from 8 hours for a simple objection, e.g., size of pineapple pieces, to 40 hours for a more complex situation, e.g., number of eggs and addition of color to eggs in egg bread. Most objections fall in the 15 to 20 hour category. Therefore, we estimate a burden of 1,200 hours (60 x 20).

The total annual estimated burden imposed by this collection of information is 1,200 hours annually.

Estimated Annual Reporting Burden					
CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.22	60	1	60	20	1,200

There are no capital costs or operating and maintenance costs associated with this collection.

13. Cost to Respondent Resulting from the Collection of Information

There are no capital costs or operating and maintenance costs associated with this collection. The estimated cost to the respondent will vary according to the nature and the complexity of the issues being addressed.

14. Annualized Cost to FDA

The estimated cost to the Federal government is that required to review the objections and requests for a hearing. As determined by knowledgeable persons, this amounts to an average of 20 hours per submission x 60 submissions equals 1,200 hours. FDA estimates that the cost of a fully supported professional employee (GS-13, step 5) would be $33.17/hour. The estimated annual cost to the Federal government is $39,804.

15. Reason for Change

There is no change to this information collection.

16. Statistical Reporting

The reporting requirements contained in this proposal are not statistical in nature and the records are not published for statistical use.

17. Display of OMB Approval Date

We are not seeking approval to exempt display of the OMB approval date on any documents that are associated with this information collection.

18. Exceptions to "Certification for Paperwork Reduction Act Submissions"

There are not exceptions to "Certification for Paperwork Reduction Act Submissions" for this collection of information.

SECTION B - Collections of information Employing Statistical Methods

The collection of data does not employ statistical methods.